

Calendar No. 410

108TH CONGRESS
1ST SESSION**S. 573**

To amend the Public Health Service Act to promote organ donation, and
for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 6, 2003

Mr. FRIST (for himself, Mr. DODD, Mr. ENZI, Mr. FITZGERALD, Mr. BENNETT, and Mr. HATCH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

NOVEMBER 24, 2003

Reported by Mr. GREGG, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Public Health Service Act to promote organ
donation, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Organ Donation and
5 Recovery Improvement Act”.

1 **TITLE I—ORGAN DONATION AND** 2 **RECOVERY**

3 **SEC. 101. INTERAGENCY TASK FORCE ON ORGAN DONA-** 4 **TION.**

5 Part H of title III of the Public Health Service Act
6 (42 U.S.C. 273 et seq.) is amended—

7 (1) by redesignating section 378 (42 U.S.C.
8 274g) as section 378E; and

9 (2) by inserting after section 377 (42 U.S.C.
10 274f) the following:

11 **“SEC. 378. INTER-AGENCY TASK FORCE ON ORGAN DONA-** 12 **TION AND RESEARCH.**

13 “(a) IN GENERAL.—The Secretary shall establish an
14 inter-agency task force on organ donation and research
15 (referred to in this section as the ‘task force’) to improve
16 the coordination and evaluation of—

17 “(1) federally supported or conducted organ do-
18 nation efforts and policies; and

19 “(2) federally supported or conducted basic,
20 clinical and health services research (including re-
21 search on preservation techniques and organ rejec-
22 tion and compatibility).

23 **“(b) COMPOSITION.—**

24 “(1) IN GENERAL.—The task force shall be
25 composed of—

1 “(A) the Surgeon General, who shall serve
2 as the chairperson; and

3 “(B) representatives to be appointed by
4 the Secretary from relevant agencies within the
5 Department of Health and Human Services (in-
6 cluding the Health Resources and Services Ad-
7 ministration, Centers for Medicare & Medicaid
8 Services, National Institutes of Health, and
9 Agency for Healthcare Research and Quality);

10 “(2) OTHER EX OFFICIO MEMBERS.—The Sec-
11 retary shall invite the following individuals to serve
12 as ex officio members of the task force:

13 “(A) A representative from the Depart-
14 ment of Transportation;

15 “(B) A representative from the Depart-
16 ment of Defense;

17 “(C) A representative from the Depart-
18 ment of Veterans Affairs;

19 “(D) A representative from the Office of
20 Personnel Management;

21 “(E) A physician representative from the
22 board of directors of the Organ Procurement
23 and Transplantation Network;

8 “(d) **TERMINATION.**—The task force may be termi-
9 nated at the discretion of the Secretary following the com-
10 pletion of at least 2 annual reports under section 378D(e).
11 Upon such termination, the Secretary shall provide for the
12 on-going coordination of federally supported or conducted
13 organ donation and research activities.”.

Part H of title III of the Public Health Service Act
(42 U.S.C 273 et seq.) is amended by inserting after sec-
tion 378, as added by section 101, the following:

21 “(a) GRANTS TO INCREASE DONATION RATES.—The
22 Secretary shall award peer-reviewed grants to public and
23 non-profit private entities, including States, to carry out
24 studies and demonstration projects to increase organ do-
25 nation and recovery rates, including living donation.

1 “(b) ORGAN DONATION PUBLIC AWARENESS PRO-
 2 GRAM.—The Secretary shall establish a public education
 3 program in cooperation with existing national public
 4 awareness campaigns to increase awareness about organ
 5 donation and the need to provide for an adequate rate of
 6 such donations.

7 “(c) DEVELOPMENT OF CURRICULA AND OTHER
 8 EDUCATION ACTIVITIES.—

9 “(1) IN GENERAL.—The Secretary, in coordina-
 10 tion with the Organ Procurement and Transplan-
 11 tation Network and other appropriate organizations,
 12 shall support the development and dissemination of
 13 model curricula to train health care professionals
 14 and other appropriate professionals (including reli-
 15 gious leaders in the community, funeral directors,
 16 and law enforcement officials) in issues surrounding
 17 organ donation, including methods to approach pa-
 18 tients and their families, cultural sensitivities, and
 19 other relevant issues.

20 “(2) HEALTH CARE PROFESSIONALS.—For pur-
 21 poses of subparagraph (A), the term ‘health care
 22 professionals’ includes—

23 “(A) medical students, residents and fel-
 24 lows, attending physicians (through continuing
 25 medical education courses and other methods);

nurses, social workers, and other allied health professionals;

~~“(B) hospital- or other health care-facility based chaplains; and~~

~~“(C) emergency medical personnel.~~

~~“(d) LIMITED DEMONSTRATION PROJECTS.—~~

~~“(1) REPORTS.—Not later than 1 year after the date of enactment of this section, the Secretary shall prepare and submit to the appropriate committees of Congress a report evaluating the ethical implications of proposals for demonstration projects to increase cadaveric donation.~~

~~“(2) AUTHORITY.—Notwithstanding section 301 of the National Organ Transplant Act (42 U.S.C. 274e), upon the submission of and consistent with the report by the Secretary under paragraph (1), the Secretary may conduct up to 3 demonstration projects to increase cadaveric donation.~~

~~“(3) DURATION.—Each project shall last no more than 3 years, and shall be conducted in a limited number of sites or areas.~~

~~“(4) REVIEW.—The Secretary shall provide for the ongoing ethical review and evaluation of such projects to ensure that such projects are administered effectively as possible and in accordance with~~

1 the stated purpose of this subsection under para-
 2 graph (2).

3 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
 4 is authorized to be appropriated to carry out this section;
 5 \$5,000,000 for fiscal year 2004, and such sums as may
 6 be necessary for each of the fiscal years 2005 through
 7 2008.

8 **“SEC. 378B. GRANTS REGARDING HOSPITAL ORGAN DONA-
 9 TION COORDINATORS.**

10 “(a) AUTHORITY.—

11 “(1) IN GENERAL.—The Secretary may award
 12 grants to qualified organ procurement organizations
 13 under section 371 to establish programs coordi-
 14 nating organ donation activities of eligible hospitals
 15 and qualified organ procurement organizations
 16 under section 371. Such activities shall be coordi-
 17 nated to increase the rate of organ donations for
 18 such hospitals.

19 “(2) ELIGIBLE HOSPITAL.—For purposes of
 20 this section, an eligible hospital is a hospital that
 21 performs significant trauma care, or a hospital or
 22 consortium of hospitals that serves a population base
 23 of not fewer than 200,000 individuals.

24 “(b) ADMINISTRATION OF COORDINATION PRO-
 25 GRAM.—A condition for the receipt of a grant under sub-

1 section (a) is that the applicant involved agree that the
 2 program under such subsection will be carried out joint-
 3 ly—

4 “(1) by representatives from the eligible hos-
 5 pital and the qualified organ procurement organiza-
 6 tion with respect to which the grant is made; and

7 “(2) by such other entities as the representa-
 8 tives referred to in paragraph (1) may designate.

9 “(c) EVALUATIONS.—Within 3 years after the award
 10 of grants under this section, the Secretary shall ensure
 11 an evaluation of programs carried out pursuant to sub-
 12 section (a) in order to determine the extent to which the
 13 programs have increased the rate of organ donation for
 14 the eligible hospitals involved. Such evaluation shall in-
 15 clude recommendations on whether the program should be
 16 expanded to include other grantees, such as hospitals.

17 “(d) MATCHING REQUIREMENT.—The Secretary may
 18 not award a grant to a qualifying organ donation entity
 19 under this section unless such entity agrees that, with re-
 20 spect to costs to be incurred by the entity in carrying out
 21 activities for which the grant was awarded, the entity shall
 22 contribute (directly or through donations from public or
 23 private entities) non-Federal contributions in cash or in
 24 kind, in an amount equal to not less than 30 percent of
 25 the amount of the grant awarded to such entity.

1 “(e) FUNDING.—For the purpose of carrying out this
 2 section, there are authorized to be appropriated
 3 \$3,000,000 for fiscal year 2004, and such sums as may
 4 be necessary for each of fiscal years 2005 through 2008.”.

5 **SEC. 103. STUDIES RELATING TO ORGAN DONATION AND**
 6 **THE RECOVERY, PRESERVATION, AND TRANS-**
 7 **PORTATION OF ORGANS.**

8 Part H of title III of the Public Health Service Act
 9 (42 U.S.C. 273 et seq.) is amended by inserting after sec-
 10 tion 378B, as added by section 102, the following:

11 **“SEC. 378C. STUDIES RELATING TO ORGAN DONATION AND**
 12 **THE RECOVERY, PRESERVATION, AND TRANS-**
 13 **PORTATION OF ORGANS.**

14 “(a) DEVELOPMENT OF SUPPORTIVE INFORMA-
 15 TION.—The Secretary, acting through the Administrator
 16 of the Health Resources and Services Administration and
 17 the Director of the Agency for Healthcare Research and
 18 Quality shall develop scientific evidence in support of ef-
 19 forts to increase organ donation and improve the recovery,
 20 preservation, and transportation of organs.

21 “(b) ACTIVITIES.—In carrying out subsection (a), the
 22 Secretary shall—

23 “(1) conduct or support evaluation research to
 24 determine whether interventions, technologies, or

1 other activities improve the effectiveness, efficiency,
 2 or quality of existing organ donation practice;

3 “(2) undertake or support periodic reviews of
 4 the scientific literature to assist efforts of profes-
 5 sional societies to ensure that the clinical practice
 6 guidelines that they develop reflect the latest sci-
 7 entific findings;

8 “(3) ensure that scientific evidence of the re-
 9 search and other activities undertaken under this
 10 section is readily accessible by the organ procure-
 11 ment workforce; and

12 “(4) work in coordination with the appropriate
 13 professional societies as well as the Organ Procure-
 14 ment and Transplantation Network and other organ
 15 procurement and transplantation organizations to
 16 develop evidence and promote the adoption of such
 17 proven practices.

18 “(e) RESEARCH, DEMONSTRATIONS, AND TRAIN-
 19 ING.—The Secretary, acting through the Administrator of
 20 the Health Resources and Services Administration and the
 21 Director of the Agency for Healthcare Research and Qual-
 22 ity, as appropriate, shall provide support for research,
 23 demonstrations, and training as appropriate, to—

24 “(1) develop a uniform clinical vocabulary for
 25 organ recovery;

1 “(2) apply information technology and tele-
2 communications to support the clinical operations of
3 organ procurement organizations;

4 “(3) enhance the skill levels of the organ pro-
5 curement workforce in undertaking quality improve-
6 ment activities; and

7 “(4) assess specific organ recovery, preserva-
8 tion, and transportation technologies.

9 “(d) **AUTHORIZATION OF APPROPRIATIONS.**—For the
10 purpose of carrying out this section, there are authorized
11 to be appropriated \$5,000,000 for fiscal year 2004, and
12 such sums as may be necessary for each of fiscal years
13 2005 through 2008.”.

14 **SEC. 104. REPORTS.**

15 Part H of title III of the Public Health Service Act
16 (42 U.S.C. 273 et seq.) is amended by inserting after sec-
17 tion 378C, as added by section 103, the following:

18 **“SEC. 378D. REPORTS.**

19 “(a) **IOM REPORT ON BEST PRACTICES.**—

20 “(1) **IN GENERAL.**—The Secretary shall enter
21 into a contract with the Institute of Medicine to con-
22 duct an evaluation of the organ donation practices of
23 organ procurement organizations, States, other
24 countries, and other appropriate organizations.

1 “(2) CONSIDERATIONS.—In conducting the
2 evaluation under paragraph (1), the Institute of
3 Medicine shall examine—

4 “(A) existing barriers to organ donation;
5 including among minority populations; and

6 “(B) best donation and recovery practices;
7 including—

8 “(i) mandated choice and presumed
9 consent;

10 “(ii) organ procurement organization
11 and provider consent practices (including
12 consent best practices);

13 “(iii) the efficacy and reach of exist-
14 ing State routine notification laws with re-
15 spect to organ procurement organizations;

16 “(iv) the impact of requests for con-
17 sent in States where registry registration
18 constitutes express consent under State
19 law; and

20 “(v) recommendations with respect to
21 achieving higher donation rates; including
22 among minority populations.

23 “(3) REPORT.—Not later than 18 months after
24 the date of enactment of this section, the Institute
25 of Medicine shall submit to the Secretary a report

1 concerning the evaluation conducted under this sub-
 2 section. Such report shall include recommendations
 3 for administrative actions and, if necessary, legisla-
 4 tion in order to replicate the best practices identified
 5 in the evaluation and to otherwise increase organ do-
 6 nation and recovery rates.

7 “(b) IOM REPORT ON LIVING DONATIONS.—

8 “(1) IN GENERAL.—The Secretary shall enter
 9 into a contract with the Institute of Medicine to con-
 10 duct an evaluation of living donation practices and
 11 procedures. Such evaluation shall include, but is not
 12 limited to an assessment of issues relating to in-
 13 formed consent and the health risks associated with
 14 living donation (including possible reduction of long-
 15 term effects).

16 “(2) REPORT.—Not later than 18 months after
 17 the date of enactment of this section, the Institute
 18 of Medicine shall submit to the Secretary a report
 19 concerning the evaluation conducted under this sub-
 20 section.

21 “(c) REPORT ON DONATION AND RECOVERY ACTIVI-
 22 TIES.—

23 “(1) IN GENERAL.—The Secretary as part of
 24 the report specified in 274d shall submit an evalua-
 25 tion concerning federally supported or conducted

organ donation and recovery activities, including donation and recovery activities evaluated or conducted under the amendments made by the Organ Donation and Recovery Improvement Act to increase organ donation and recovery rates.

~~“(2) REQUIREMENTS.—To the extent practicable, each evaluation submitted under paragraph (1) shall—~~

~~“(A) evaluate the effectiveness of activities; identify best practices; and make recommendations regarding the adoption of best practices with respect to organ donation and recovery; and~~

~~“(B) assess organ donation and recovery activities that are recently completed, ongoing, or planned.”.~~

SEC. 105. TECHNICAL AMENDMENT CONCERNING ORGAN PURCHASES.

Section 301(c)(2) of the National Organ Transplant Act (42 U.S.C. 274e(c)(2)) is amended by adding at the end the following: “Such term does not include familial, emotional, psychological, or physical benefit to an organ donor, recipient, or any other party to an organ donation event.”.

TITLE II—LIVING DONATION EXPENSES

SEC. 201. REIMBURSEMENT OF TRAVEL AND SUBSISTENCE EXPENSES INCURRED TOWARD LIVING ORGAN DONATION.

Section 377 of the Public Health Service Act (42 U.S.C. 274f) is amended to read as follows:

“SEC. 377. REIMBURSEMENT OF TRAVEL AND SUBSISTENCE EXPENSES INCURRED TOWARD LIVING ORGAN DONATION.

“(a) IN GENERAL.—The Secretary may award grants to States, transplant centers, qualified organ procurement organizations under section 371, or other public or private entities for the purpose of—

“(1) providing for the reimbursement of travel and subsistence expenses incurred by individuals toward making living donations of their organs (in this section referred as ‘donating individuals’); and

“(2) providing for the reimbursement of such incidental nonmedical expenses that are so incurred as the Secretary determines by regulation to be appropriate.

“(b) PREFERENCE.—The Secretary shall, in carrying out subsection (a), give preference to those individuals

1 that the Secretary determines are more likely to be other-
 2 wise unable to meet such expenses.

3 ~~“(e) CERTAIN CIRCUMSTANCES.—The Secretary~~
 4 ~~may, in carrying out subsection (a), consider—~~

5 ~~“(1) the term ‘donating individuals’ as includ-~~
 6 ~~ing individuals who in good faith incur qualifying ex-~~
 7 ~~penses toward the intended donation of an organ but~~
 8 ~~with respect to whom, for such reasons as the Sec-~~
 9 ~~retary determines to be appropriate, no donation of~~
 10 ~~the organ occurs; and~~

11 ~~“(2) the term ‘qualifying expenses’ as including~~
 12 ~~the expenses of having relatives or other individuals,~~
 13 ~~not to exceed 2, who accompany or assist the donat-~~
 14 ~~ing individual for purposes of subsection (a) (subject~~
 15 ~~to making payment for only such types of expenses~~
 16 ~~as are paid for donating individual).~~

17 ~~“(d) RELATIONSHIP TO PAYMENTS UNDER OTHER~~
 18 ~~PROGRAMS.—An award may be made under subsection (a)~~
 19 ~~only if the applicant involved agrees that the award will~~
 20 ~~not be expended to pay the qualifying expenses of a donat-~~
 21 ~~ing individual to the extent that payment has been made,~~
 22 ~~or can reasonably be expected to be made, with respect~~
 23 ~~to such expenses—~~

1 “(1) under any State compensation program;
2 under an insurance policy; or under any Federal or
3 State health benefits program;

4 “(2) by an entity that provides health services
5 on a prepaid basis; or

6 “(3) by the recipient of the organ.

7 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
8 purpose of carrying out this section, there is authorized
9 to be appropriated \$5,000,000 for fiscal year 2004, and
10 such sums as may be necessary for each of fiscal years
11 2005 through 2008.”.

12 **TITLE III—ORGAN REGISTRIES**

13 **SEC. 301. ADVISORY COMMITTEE.**

14 Part H of title III of the Public Health Service Act
15 (42 U.S.C. 273 et seq.) is amended by inserting after sec-
16 tion 371 the following:

17 **“SEC. 371A. ADVISORY COMMITTEE.**

18 “(a) IN GENERAL.—Not later than 6 months after
19 enactment, the Secretary shall establish an advisory com-
20 mittee to study existing organ donor registries and make
21 recommendations to Congress regarding the costs, bene-
22 fits, and expansion of such registries.

23 “(b) MEMBERSHIP.—The committee shall be com-
24 posed of 10 members of whom—

1 “(1) at least 1 member shall be a physician
2 with experience performing transplants;

3 “(2) at least 1 member shall have experience in
4 organ recovery;

5 “(3) at least 1 member shall be representative
6 of an organization with experience conducting na-
7 tional awareness campaigns and donor outreach;

8 “(4) at least 1 member shall be representative
9 of a State with an existing donor registry;

10 “(5) at least 1 member shall have experience
11 with national information systems where coordina-
12 tion occurs with State-based systems; and

13 “(6) at least 1 member shall represent donor
14 families, transplant recipients, and those awaiting
15 transplantation.

16 “(c) INITIAL MEETING.—Not later than 30 days
17 after the date on which all members of the committee have
18 been appointed, the committee shall hold its first meeting.

19 “(d) MEETINGS.—The committee shall meet at the
20 call of the Chairman who shall be selected by the Sec-
21 retary.

22 “(e) COMPENSATION.—Each member of the com-
23 mittee shall not receive compensation for services provided
24 under this section.

1 “(f) TRAVEL EXPENSES.—The members of the com-
 2 mittee shall be allowed travel expenses, including per diem
 3 in lieu of subsistence, at rates authorized for employees
 4 of agencies under subchapter I of chapter 57 of title 5,
 5 United States Code, while away from their homes or reg-
 6 ular places of business in the performance of services for
 7 the committee.

8 “(g) ADMINISTRATIVE SUPPORT.—The Secretary
 9 shall ensure that the committee is provided with adminis-
 10 trative support or any other technical assistance that such
 11 committee needs in carrying out its duties.

12 “(h) PERMANENT COMMITTEE.—Section 14 of the
 13 Federal Advisory Committee Act shall not apply to the
 14 committee established under this section.

15 “(i) REPORT.—Not later than 1 year after the date
 16 on which the committee is established under subsection
 17 (a), the committee shall prepare and submit to Congress
 18 a report regarding the status of organ donor registries,
 19 current best practices, the effect of organ donor registries
 20 on organ donation rates, the merits of expanding organ
 21 donor registries, issues relating to consent, the efficacy of
 22 current privacy protections, potential forms of technical
 23 assistance, and recommendations regarding improving the
 24 effectiveness and establishing formal linkages between
 25 organ donor registries.

7 Part H of title III of the Public Health Service Act
8 (42 U.S.C. 273 et seq.), as amended by section 301, is
9 further amended by inserting after section 371A the fol-
10 lowing:

12 “The Secretary shall by contract establish and main-
13 tain a registry of individuals who have served as living
14 organ donors for the purpose of evaluating the long-term
15 health effects associated with living organ donations.”.

Section 371(a) of the Public Health Service Act (42 U.S.C. 273(a)) is amended by striking paragraph (3).

21 *This Act may be cited as the “Organ Donation and*
22 *Recovery Improvement Act”.*

24 (a) PUBLIC AWARENESS OF NEED FOR ORGAN DONA-
25 TION.—It is the sense of Congress that the Federal Govern-

1 *ment should carry out programs to educate the public with*
 2 *respect to organ donation, including the need to provide for*
 3 *an adequate rate of such donations.*

4 *(b) FAMILY DISCUSSIONS OF ORGAN DONATIONS.—*
 5 *Congress recognizes the importance of families pledging to*
 6 *each other to share their lives as organ and tissue donors*
 7 *and acknowledges the importance of discussing organ and*
 8 *tissue donation as a family.*

9 *(c) LIVING DONATIONS OF ORGANS.—Congress—*

10 *(1) recognizes the generous contribution made by*
 11 *each living individual who has donated an organ to*
 12 *save a life; and*

13 *(2) acknowledges the advances in medical tech-*
 14 *nology that have enabled organ transplantation with*
 15 *organs donated by living individuals to become a via-*
 16 *ble treatment option for an increasing number of pa-*
 17 *tients.*

18 **SEC. 3. REIMBURSEMENT OF TRAVEL AND SUBSISTENCE**
 19 **EXPENSES INCURRED TOWARD LIVING**
 20 **ORGAN DONATION.**

21 *Section 377 of the Public Health Service Act (42*
 22 *U.S.C. 274f) is amended to read as follows:*

1 **“SEC. 377. REIMBURSEMENT OF TRAVEL AND SUBSISTENCE**
 2 **EXPENSES INCURRED TOWARD LIVING**
 3 **ORGAN DONATION.**

4 “(a) *IN GENERAL.*—*The Secretary may award grants*
 5 *to States, transplant centers, qualified organ procurement*
 6 *organizations under section 371, or other public or private*
 7 *entities for the purpose of—*

8 “(1) *providing for the reimbursement of travel*
 9 *and subsistence expenses incurred by individuals to-*
 10 *ward making living donations of their organs (in this*
 11 *section referred to as ‘donating individuals’); and*

12 “(2) *providing for the reimbursement of such in-*
 13 *cidental nonmedical expenses that are so incurred as*
 14 *the Secretary determines by regulation to be appro-*
 15 *priate.*

16 “(b) *PREFERENCE.*—*The Secretary shall, in carrying*
 17 *out subsection (a), give preference to those individuals that*
 18 *the Secretary determines are more likely to be otherwise un-*
 19 *able to meet such expenses.*

20 “(c) *CERTAIN CIRCUMSTANCES.*—*The Secretary may,*
 21 *in carrying out subsection (a), consider—*

22 “(1) *the term ‘donating individuals’ as including*
 23 *individuals who in good faith incur qualifying ex-*
 24 *penses toward the intended donation of an organ but*
 25 *with respect to whom, for such reasons as the Sec-*

1 retary determines to be appropriate, no donation of
2 the organ occurs; and

3 “(2) the term ‘qualifying expenses’ as including
4 the expenses of having relatives or other individuals,
5 not to exceed 2, who accompany or assist the donating
6 individual for purposes of subsection (a) (subject to
7 making payment for only those types of expenses that
8 are paid for a donating individual).

9 “(d) *RELATIONSHIP TO PAYMENTS UNDER OTHER*
10 *PROGRAMS.*—An award may be made under subsection (a)
11 only if the applicant involved agrees that the award will
12 not be expended to pay the qualifying expenses of a donat-
13 ing individual to the extent that payment has been made,
14 or can reasonably be expected to be made, with respect to
15 such expenses—

16 “(1) under any State compensation program,
17 under an insurance policy, or under any Federal or
18 State health benefits program;

19 “(2) by an entity that provides health services on
20 a prepaid basis; or

21 “(3) by the recipient of the organ.

22 “(e) *DEFINITIONS.*—For purposes of this section:

23 “(1) The term ‘donating individuals’ has the
24 meaning indicated for such term in subsection (a)(1),
25 subject to subsection (c)(1).

8 *SEC. 4. PUBLIC AWARENESS; STUDIES AND DEMONSTRATIONS.*
9

13 “SEC. 377A. PUBLIC AWARENESS; STUDIES AND DEM-
14 ONSTRATIONS.

21 “(b) *STUDIES AND DEMONSTRATIONS.*—*The Secretary*
22 *may make peer reviewed grants or contracts to public and*
23 *nonprofit private entities for the purpose of carrying out*
24 *studies and demonstration projects to increase organ dona-*
25 *tion and recovery rates, including living donation.*

1 “(c) *GRANTS TO STATES.*—*The Secretary may make*
 2 *grants to States for the purpose of assisting States in car-*
 3 *rying out organ donor awareness, public education and out-*
 4 *reach activities, and programs designed to increase the*
 5 *number of organ donors within the State, including living*
 6 *donors. To be eligible, each State shall—*

7 “(1) *submit an application to the Department in*
 8 *the form prescribed;*

9 “(2) *establish yearly benchmarks for improve-*
 10 *ment in organ donation rates in the State; and*

11 “(3) *report to the Secretary on an annual basis*
 12 *a description and assessment of the State’s use of*
 13 *these grant funds, accompanied by an assessment of*
 14 *initiatives for potential replication in other States.*

15 *Funds may be used by the State or in partnership with*
 16 *other public agencies or private sector institutions for edu-*
 17 *cation and awareness efforts, information dissemination,*
 18 *activities pertaining to the State donor registry, and other*
 19 *innovative donation specific initiatives, including living*
 20 *donation.*

21 “(d) *EDUCATIONAL ACTIVITIES.*—*The Secretary, in*
 22 *coordination with the Organ Procurement and Transplan-*
 23 *tation Network and other appropriate organizations, shall*
 24 *support the development and dissemination of educational*
 25 *materials to inform health care professionals and other ap-*

1 *proprie professionals in issues surrounding organ, tissue,*
 2 *and eye donation including evidence-based proven methods*
 3 *to approach patients and their families, cultural sensitivi-*
 4 *ties, and other relevant issues.*

5 “(e) *AUTHORIZATION OF APPROPRIATIONS.—For the*
 6 *purpose of carrying out this section, there are authorized*
 7 *to be appropriated \$15,000,000 for fiscal year 2004, and*
 8 *such sums as may be necessary for each of the fiscal years*
 9 *2005 through 2008. Such authorization of appropriations*
 10 *is in addition to any other authorizations of appropriations*
 11 *that are available for such purpose.*

12 **“SEC. 377B. GRANTS REGARDING HOSPITAL ORGAN DONA-**
 13 **TION COORDINATORS.**

14 “(a) *AUTHORITY.—*

15 “(1) *IN GENERAL.—The Secretary may award*
 16 *grants to qualified organ procurement organizations*
 17 *and hospitals under section 371 to establish programs*
 18 *coordinating organ donation activities of eligible hos-*
 19 *pitals and qualified organ procurement organizations*
 20 *under section 371. Such activities shall be coordinated*
 21 *to increase the rate of organ donations for such hos-*
 22 *pitals.*

23 “(2) *ELIGIBLE HOSPITAL.—For purposes of this*
 24 *section, an eligible hospital is a hospital that per-*
 25 *forms significant trauma care, or a hospital or con-*

1 *sortium of hospitals that serves a population base of*
 2 *not fewer than 200,000 individuals.*

3 “(b) *ADMINISTRATION OF COORDINATION PROGRAM.*—
 4 *A condition for the receipt of a grant under subsection (a)*
 5 *is that the applicant involved agree that the program under*
 6 *such subsection will be carried out jointly—*

7 “(1) *by representatives from the eligible hospital*
 8 *and the qualified organ procurement organization*
 9 *with respect to which the grant is made; and*

10 “(2) *by such other entities as the representatives*
 11 *referred to in paragraph (1) may designate.*

12 “(c) *REQUIREMENTS.*—*Each entity receiving a grant*
 13 *under subsection (a) shall—*

14 “(1) *establish joint organ procurement organiza-*
 15 *tion and hospital designated leadership responsibility*
 16 *and accountability for the project;*

17 “(2) *develop mutually agreed upon overall*
 18 *project performance goals and outcome measures, in-*
 19 *cluding interim outcome targets; and*

20 “(3) *collaboratively design and implement an*
 21 *appropriate data collection process to provide ongoing*
 22 *feedback to hospital and organ procurement organiza-*
 23 *tion leadership on project progress and results.*

24 “(d) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*
 25 *tion shall be construed to interfere with regulations in force*

1 *on the date of enactment of the Organ Donation and Recov-*
2 *ery Improvement Act.*

3 “(e) *EVALUATIONS.*—*Within 3 years after the award*
4 *of grants under this section, the Secretary shall ensure an*
5 *evaluation of programs carried out pursuant to subsection*
6 *(a) in order to determine the extent to which the programs*
7 *have increased the rate of organ donation for the eligible*
8 *hospitals involved.*

9 “(f) *MATCHING REQUIREMENT.*—*The Secretary may*
10 *not award a grant to a qualifying organ donation entity*
11 *under this section unless such entity agrees that, with re-*
12 *spect to costs to be incurred by the entity in carrying out*
13 *activities for which the grant was awarded, the entity shall*
14 *contribute (directly or through donations from public or*
15 *private entities) non-Federal contributions in cash or in*
16 *kind, in an amount equal to not less than 30 percent of*
17 *the amount of the grant awarded to such entity.*

18 “(g) *FUNDING.*—*For the purpose of carrying out this*
19 *section, there are authorized to be appropriated \$3,000,000*
20 *for fiscal year 2004, and such sums as may be necessary*
21 *for each of fiscal years 2005 through 2008.”.*

1 **SEC. 5. STUDIES RELATING TO ORGAN DONATION AND THE**
 2 **RECOVERY, PRESERVATION, AND TRANSPOR-**
 3 **TATION OF ORGANS.**

4 *Part H of title III of the Public Health Service Act*
 5 *(42 U.S.C. 273 et seq.) is amended by inserting after section*
 6 *377B, as added by section 4, the following:*

7 **“SEC. 377C. STUDIES RELATING TO ORGAN DONATION AND**
 8 **THE RECOVERY, PRESERVATION, AND TRANS-**
 9 **PORTATION OF ORGANS.**

10 *“(a) DEVELOPMENT OF SUPPORTIVE INFORMATION.—*
 11 *The Secretary, acting through the Director of the Agency*
 12 *for Healthcare Research and Quality shall develop scientific*
 13 *evidence in support of efforts to increase organ donation*
 14 *and improve the recovery, preservation, and transportation*
 15 *of organs.*

16 *“(b) ACTIVITIES.—In carrying out subsection (a), the*
 17 *Secretary shall—*

18 *“(1) conduct or support evaluation research to*
 19 *determine whether interventions, technologies, or other*
 20 *activities improve the effectiveness, efficiency, or qual-*
 21 *ity of existing organ donation practice;*

22 *“(2) undertake or support periodic reviews of the*
 23 *scientific literature to assist efforts of professional so-*
 24 *cieties to ensure that the clinical practice guidelines*
 25 *that they develop reflect the latest scientific findings;*

1 “(3) ensure that scientific evidence of the re-
 2 search and other activities undertaken under this sec-
 3 tion is readily accessible by the organ procurement
 4 workforce; and

5 “(4) work in coordination with the appropriate
 6 professional societies as well as the Organ Procure-
 7 ment and Transplantation Network and other organ
 8 procurement and transplantation organizations to de-
 9 velop evidence and promote the adoption of such prov-
 10 en practices.

11 “(c) *RESEARCH AND DISSEMINATION.*—The Secretary,
 12 acting through the Director of the Agency for Healthcare
 13 Research and Quality, as appropriate, shall provide sup-
 14 port for research and dissemination of findings, to—

15 “(1) develop a uniform clinical vocabulary for
 16 organ recovery;

17 “(2) apply information technology and tele-
 18 communications to support the clinical operations of
 19 organ procurement organizations;

20 “(3) enhance the skill levels of the organ procure-
 21 ment workforce in undertaking quality improvement
 22 activities; and

23 “(4) assess specific organ recovery, preservation,
 24 and transportation technologies.

1 “(d) *AUTHORIZATION OF APPROPRIATIONS.*—For the
 2 purpose of carrying out this section, there are authorized
 3 to be appropriated \$2,000,000 for fiscal year 2004, and
 4 such sums as may be necessary for each of fiscal years 2005
 5 through 2008.”.

6 **SEC. 6. REPORT RELATING TO ORGAN DONATION AND THE**
 7 **RECOVERY, PRESERVATION, AND TRANSPOR-**
 8 **TATION OF ORGANS.**

9 *Part H of title III of the Public Health Service Act*
 10 *(42 U.S.C. 273 et seq.) is amended by inserting after section*
 11 *377C, as added by section 5, the following:*

12 **“SEC. 377D. REPORT RELATING TO ORGAN DONATION AND**
 13 **THE RECOVERY, PRESERVATION, AND TRANS-**
 14 **PORTATION OF ORGANS.**

15 “(a) *IN GENERAL.*—Not later than December 31, 2005,
 16 and every 2 years thereafter, the Secretary shall report to
 17 the appropriate committees of Congress on the activities of
 18 the Department carried out pursuant to this part, including
 19 an evaluation describing the extent to which the activities
 20 have affected the rate of organ donation and recovery.

21 “(b) *REQUIREMENTS.*—To the extent practicable, each
 22 report submitted under subsection (a) shall—

23 “(1) *evaluate the effectiveness of activities, iden-*
 24 *tify effective activities, and disseminate such findings*
 25 *with respect to organ donation and recovery;*

1 “(2) assess organ donation and recovery activi-
 2 ties that are recently completed, ongoing, or planned;
 3 and

4 “(3) evaluate progress on the implementation of
 5 the plan required under subsection (c)(4).

6 “(c) *INITIAL REPORT REQUIREMENTS.*—The initial
 7 report under subsection (a) shall include the following:

8 “(1) An evaluation of the organ donation prac-
 9 tices of organ procurement organizations, States,
 10 other countries, and other appropriate organizations
 11 including an examination across all populations, in-
 12 cluding those with low organ donation rates, of—

13 “(A) existing barriers to organ donation;
 14 and

15 “(B) the most effective donation and recov-
 16 ery practices.

17 “(2) An evaluation of living donation practices
 18 and procedures. Such evaluation shall include an as-
 19 sessment of issues relating to informed consent and
 20 the health risks associated with living donation (in-
 21 cluding possible reduction of long-term effects).

22 “(3) An evaluation of—

23 “(A) federally supported or conducted organ
 24 donation efforts and policies, as well as federally
 25 supported or conducted basic, clinical, and

1 *health services research (including research on*
 2 *preservation techniques an organ rejection and*
 3 *compatibility); and*

4 *“(B) the coordination of such efforts across*
 5 *relevant agencies within the Department and*
 6 *throughout the Federal Government.*

7 *“(4) An evaluation of the costs and benefits of*
 8 *State donor registries, including the status of existing*
 9 *State donor registries, the effect of State donor reg-*
 10 *istries on organ donation rates, issues relating to con-*
 11 *sent, and recommendations regarding improving the*
 12 *effectiveness of State donor registries in increasing*
 13 *overall organ donation rates.*

14 *“(5) A plan to improve federally supported or*
 15 *conducted organ donation and recovery activities, in-*
 16 *cluding, when appropriate, the establishment of base-*
 17 *lines and benchmarks to measure overall outcomes of*
 18 *these programs. Such plan shall provide for the ongo-*
 19 *ing coordination of federally supported or conducted*
 20 *organ donation and research activities.”.*

21 **SEC. 7. NATIONAL LIVING DONOR MECHANISMS.**

22 *Part H of title III of the Public Health Service Act*
 23 *(42 U.S.C. 273 et seq.), is amended by inserting after sec-*
 24 *tion 371 the following:*

1 **“SEC. 371A. NATIONAL LIVING DONOR MECHANISMS.**

2 *“The Secretary is authorized to establish and main-*
 3 *tain mechanisms to evaluate the long-term effects associated*
 4 *with living organ donations by individuals who have served*
 5 *as living donors.”.*

6 **SEC. 8. STUDY.**

7 *Not later than December 31, 2004, the Secretary of*
 8 *Health and Human Services, in consultation with appro-*
 9 *priate entities, including advocacy groups representing*
 10 *those populations that are likely to be disproportionately*
 11 *affected by proposals to increase cadaveric donation, shall*
 12 *submit to the appropriate committees of Congress a report*
 13 *that evaluates the ethical implications of such proposals.*

14 **SEC. 9. QUALIFIED ORGAN PROCUREMENT ORGANIZA-**
 15 **TIONS.**

16 *Section 371(a) of the Public Health Service Act (42*
 17 *U.S.C. 273(a)) is amended by striking paragraph (3).*

Calendar No. 410

108TH CONGRESS
1ST SESSION

S. 573

A BILL

To amend the Public Health Service Act to
promote organ donation, and for other purposes.

NOVEMBER 24, 2003

Reported with an amendment